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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,123	11/26/2003	Theodorus Cornelis Schaap	I-1998.407 US D2	1322

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,123	SCHAAP ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) *1-15,21,22 and 24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election

1. Applicant's amendment filed on 10/4/05 is acknowledged. Applicant's election of Group IV, claims 16-20 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 1-22 and 24-29 are pending in the application.

Claim 16 has been amended.

Claim 23 is canceled.

Claims 16-20 are under examination.

Claims 1-15, 21, 22 and 24-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/4/05.

Information Disclosure Statement

3. Information Disclosure Statement filed on 11/26/03 is acknowledged and a signed copy is attached to this Office action.

Priority

4. This application 10/723,123 is a division of 09/749,233, now U.S.Patent: 6,680,061, is a division of 09/411,578 , Patent Number: 6,203,801 .

Specification - Informalities

5. Applicant is advised to update the status of all priority application and this should appear as the first sentence of the specification following the title, preferably as a separate paragraph. For example: 10/723,123 is a division of 09/749,233, now U.S.Patent: 6,680,061

For example: 10/723,123 is a division of 09/749,233, now U.S.Patent: 6,680,061

Claim Rejections - 35 USC 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition for the protection of poultry chicken against *E. tenella* comprising the amino acid sequence of SEQ.ID NO: 3 and a pharmaceutically acceptable carrier does not reasonably provide enablement for a vaccine composition for the protection of poultry chicken against *Eimeria* comprising an amino acid sequence that shares at least 70% sequence homology with SEQ.ID.NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art how to make and use the invention commensurate with the scope of the claimed invention without undue experimentation and includes an analysis of: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

With regard to %identity, the specification is not enabled for a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO: 3 because it is

unclear to one skilled in the art what sequences are embraced by the claim and what point mutation, deletions, insertions and rearrangements have been done to an isolated peptide which would result in a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO 3. If it is unclear to one skilled in the art what sequences are embraced by a claim which is based on a specification to determine percent homology which would give rise to an isolated polypeptide which has 70% sequence homology with SEQ.ID.NO 3, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

The specification provides guidance and direction with regard to an isolated hydrophilic polypeptide comprising an amino acid sequence as set forth in the SEQ.ID.NO: 3 (example 1 and 2) which is designated as peroxidoxin-like polypeptide. However, Applicant has not set forth which amino acid (s) can be deleted or inserted or substituted in the polypeptide (SEQ.ID.NO 3) to give rise to a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO 3. After these alterations or modifications whether the polypeptide can still retain the activity as presently claimed is not set forth clearly in the specification.

It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein (70%

homology) and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex (see IDS 11/26/03, AS, Bowie et al. Science, Vol. 247: 1990; p. 1306; p. 1308) and is well outside the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in protein and the result of such modifications is unpredictable based on the instant disclosure.

With regard to function of a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO 3, Houghten et al. (see IDS 11/26/03 AR, Vaccines, 1986, Edited by Fred Brown: Cold Spring Harbor Laboratory) teach that changes/modifications (addition, substitution, deletion or inversion) of one or more amino acids in a polypeptide will alter antigenic determinants and therefore affect antibody production (p. 21) as well as antibody binding. Houghten et al. also teach that "... combined effects of multiple changes in an antigenic determinant could result in a loss of [immunological] protection." and "A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies..." (p. 24). Houghten et al. teach that point mutations at one key antigen residue could eliminate the ability of an antibody to recognize this altered antigen (p. 24). It is not always possible to make the variants that retain immunodominant regions and immunological activity if the regions have been altered. Therefore, a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO: 3 would result in a peptide without any function.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polypeptide in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes made in the protein to obtain a polypeptide comprising an amino acid sequence that shares at least 70% homology with SEQ.ID.NO 3 renders activity unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim Rejections - 35 USC 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague in reciting "one immunogen selected from the group consisting of" because there is only one hydrophilic polypeptide present in the claim.

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 16-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Karkhanis et al 1991 ((see IDS 11/26/03, AJ, Infection and Immunity, 59; 983-989).

Claims are directed to a vaccine composition for the protection of poultry chicken against *Eimeria* comprising an amino acid sequence that shares at least 70% sequence homology with SEQ.ID.NO: 3. Karkhanis et al 1991 disclose a vaccine composition comprising E. *tenella* polypeptides prepared from sporulated oocysts and sporozoites. Sporulated oocysts and sporozoites were sonicated in PBS. The sonicated material was supplemented with 0.1% Zwittergent and extracted for 18 hours. Following centrifugation the supernatant was subjected to gel filtration, which yielded 26kD and 22 kD polypeptides (see abstract, page 983, right column and figure 11 and 12). The claimed vaccine comprising hydrophilic polypeptides were present in the supernatant of extracts obtained from *E.tenella* sporulated oocysts and sporozoites of Karkhanis et al. The supernatant (hydrophilic portion) of the extract was soluble in PBS and hence contains hydrophilic polypeptides of *E. tenella.* The (i.e., immunogen) composition further comprises an adjuvant and thus read on claim 17 (see page 984, left column, first and second paragraph). The composition comprises 26kD immunogen and minor 21kD, 14kD immunogens of *E.tenella* (see fraction V in figure 2 and figure 7). Therefore, the disclosed composition reads on the claim 18. Fractions were pooled and concentrated by lyophilization (see page 984, left column, lines4-5) in a powder form and thus the disclosed composition meets the claim 20 limitation. Applicant's use of the open-ended term "comprising "in claims 16 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the vaccine composition inherently comprises the hydrophilic polypeptides that comprise an amino acid sequence as set forth in the SEQ.ID.NO: 3. Thus the prior art anticipated the claimed invention. In the absence of evidence to the contrary the disclosed prior art vaccine and the

claimed vaccine are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed vaccine with the vaccine of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Remarks

12. No claims are allowed.

Conclusion

13. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

MARK NAVARRO
PRIMARY EXAMINER